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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO..	CONFIRMATION NO.
10/628,308	07/29/2003	Julie Hazel Campbell	229752001220	4466

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EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,308	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003 and 03 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/763,359.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

On lines 1, 2, 3, 4 and 7, "the present invention" includes legal phraseology and can be implied, and therefore should be deleted.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. The use of the trademarks TEFLON and DACRON has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. If Tenckhoff Acute Peritoneal Dialysis Catheter is also a trademark, it too must be capitalized. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. The disclosure is objected to because of the following informalities:

a) The brief description of Figure 2 uses A, B and C to indicate different parts of the figure, but there is no A, B or C in Figure 2.

b) On line 1 of [0018], "for" should be changed to --from--.

c) On line 3 of [0062], "tubuler" should be changed to --tubular--.

Appropriate correction is required.

Claim Objections

5. Claims 7, 13, 23, 25, 26 and 28 are objected to because of the following informalities:

a) Claim 7, line 1, --comprising-- should be inserted after "graft".

b) Claim 7, line 3, "moulding" should be changed to --molding-- for consistent spelling.

c) Claim 13, line 3, "moulding" should be changed to --molding-- for consistent spelling.

d) Claim 23, line 2, a comma should be inserted after "produced".

e) Claim 23, lines 3 and 5, --support-- should be inserted after "molding".

f) Claims 25 and 26, line 1, --substitute-- should be inserted after "isolated".

g) Claim 28, line 2, "mold" should be changed to --molding--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 20, 21, 24, 25, 27-30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 12 is indefinite because it is a product claim dependent on a method claim. It appears that "isolated tissue" on line 1 should be changed to --method--, and will so be interpreted for examination purposes.

8. Claims 20 and 21 are indefinite because it is unclear what is encompassed by an equivalent to silastic tubing. What characteristic must the material have to be considered an equivalent? The scope of the claim cannot be determined.

9. Claim 24 is indefinite because it is a product claim that is dependent on a method claim. It appears that claim 24 should be dependent on claim 23 rather than on claim 22, and will so be interpreted for examination purposes.

10. Claim 25 is indefinite because it is a product claim that is dependent on a method claim. It appears that claim 25 should be dependent on claims 22 or 23 rather than on claims 18 or 19, and will so be interpreted for examination purposes.

11. Claim 27 recites the limitation "the damaged blood vessel" in line 2. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 27 recites the limitation "said substitute tissue" in line 3. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 32 contains "Tenckhoff Acute Peritoneal Dialysis Catheter", which may be a trademark/trade name. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to

identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a catheter and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-16, 18, 20, 21 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Sparks (USPN 3,625,198, as cited in applicant's IDS).

Sparks discloses a method for growing a graft structure in a patient's own body with all the limitations of claims 1, 7, 13, 18 and 27. Claim 1 is a product-by-process claim, and according to MPEP § 2113, this claim is not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. Therefore, the only structural element required by this claim is an isolated tissue comprising granulation tissue, wherein the tissue is capable of being used as a vascular graft. See Figure 13 for isolated tissue comprising granulation tissue (G) capable of being used as vascular graft (column 1, lines 57-60). See Figures 5-13 for method of producing a substitute blood vessel comprising granulation tissue. The body cavity is being interpreted by the Examiner to be the space made in the layer of muscle overlying the rib cage by

the flat spatula-shaped pathfinder (60). Applicant should note that [0074] of the specification, 1-10 weeks is stated as a suitable period of time for a molding support to be inside a body cavity to produce the desired granulation tissue before the molding support is removed from the cavity. Sparks discloses removing the molding support with the isolated tissue grafts formed thereon after 2-3 months of the molding support being in the body. It is therefore inherent that the tissue formed within that 2-3 months comprises granulation tissue. With respect to claim 27, it is inherent that the isolated tissue in the form of a tubular graft comprising granulation tissue will be used to treat a diseased blood vessel. There is no reason to use a vascular graft to replace a healthy blood vessel.

With respect to claims 2 and 8, it is inherent that, as a part of the inflammatory response of wound healing, the granulation tissue will be covered by non-thrombogenic mesothelial cells.

Claims 3, 9 and 14, see Figure 2 for molding support being a tubular molding (14).

With respect to claims 4, 10 and 18, it is inherent that, as a part of the inflammatory response of wound healing, the tubular tissue section will comprise living myofibroblasts within the granulation tissue.

Claims 5, 6, 11, 12, 15 and 16, see column 2, lines 15-16 for tissue being suitable for use as a substitute artery.

Claim 20, see column 2, lines 21-22 for tubular molding being plastic, which Examiner is broadly interpreting as an equivalent to silastic tubing.

Claim 21, see column 3, line 75 for incision of 3 inches being made to remove the die cluster (each die being a molding structure) from the body. Because there are three dies as shown in Figure 1, it is inherent that each die will have a diameter within the required range. See

column 4, lines 38-42 for three grafts formed on dies having a length, when sewn together, of 19 inches. It is therefore inherent that each die (molding structure) has a length within the given range.

Claims 28 and 29 do not further limit the claimed invention of a method for treating atherosclerosis or other blood vessel. The method simply requires grafting a substitute blood vessel comprising myofibroblasts within the granulation tissue. The method in which the graft is formed does not affect or limit the method of treating.

Claim 30, see column 1, lines 56-60 for treatment of human subject.

16. Claims 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Moukheibir (USPN 4,490,137, as cited in applicant's IDS).

Moukheibir discloses a peritoneal dialysis catheter with all the elements of claims 31 and 32. See column 1, lines 13-20 for a Tenckhoff peritoneal dialysis catheter, which is disclosed in [0038] and [0066] of the specification as being a suitable prosthetic device. Therefore, the prosthetic device has an elongated outer tubular member with perforations (18), inner elongated member and external portion. The inner elongated member comprises a tube around which vascular or non-vascular tissue would be capable of growing. Applicant is reminded that claim 31 is a product claim of a prosthetic device. Because the catheter of Moukheibir is capable of performing the functional limitations of the claim, the limitations are met by the prior art.

Claim 33 is does not further limit the invention of the embodiment that includes the outer elongated tubular member having perforations, as taught by Moukheibir.

With respect to claim 34, because the prosthetic device is a Tenckhoff peritoneal dialysis catheter, it will have perforations (18) of the specified size.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks in view of Winston et al. (USPN 6,117,166, as cited in applicant's IDS).

Sparks discloses a method of producing an isolated substitute blood vessel with all the elements of claim 23, but is silent to the substitute blood vessel being maintained in a frozen state. Applicant should note that this is a product claim, wherein the only structural limitations required is an isolated substitute blood vessel comprising granulation tissue with myofibroblasts maintained in a frozen state. How that isolated substitute blood vessel is formed does not affect or limit the blood vessel. Winston et al. teaches a method for grafting blood vessel tissue wherein the vascular graft has been cryogenically frozen in order to reduce the risk of graft rejection in the patient by inactivating or eliminating tissue antigens. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings Winston et al. to modify the isolated substitute blood vessel of Sparks so that it is maintained in a

frozen state in order to reduce the risk of graft rejection in the patient by inactivating or eliminating tissue antigens. See column 3, lines 40-46.

Claims 24 and 26 do not further limit the claimed invention of an isolated substitute blood vessel. The body cavity in which the substitute blood vessel is formed and the material of the molding support do not affect or limit the blood vessel.

Claim 25, see column 1, lines 56-60 for the mammal being a human.

19. Claims 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks.

Sparks discloses a method of producing substitute tissue and a substitute blood vessel with all the elements of claims 13 and 18. Sparks does not disclose expressly that the molding support is a biodegradable matrix, as required by claims 17 and 22. However, it appears in column 2, lines 54-64 that the molding support can include Teflon. Applicant discloses in [0087] of the specification that the molding support can be made from Teflon, as an alternative to a biodegradable matrix. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the molding be made from a biodegradable matrix because applicant has not disclosed that the specified molding support material provides an advantage, is used for a particular purpose, or solves a stated problem over Teflon or any of the other materials listed in [0087]. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the molding support of Teflon or any of the other materials listed in [0087] because the ability for the granulation tissue to be formed thereon is not affected by the material of the molding support.

Therefore, it would have been an obvious matter of design choice to modify Sparks to obtain the invention as specified in claims 17 and 22.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

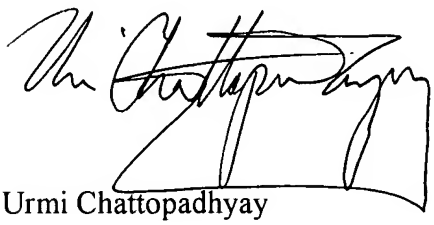
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 18 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,626,823. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the patent includes every limitation of claims 18 and 19 of the application. Claims 18 and 19 are broader in scope than claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

Art Unit 3738